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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,649	07/30/2003	Nigel Robert Arnold Beeley	18528.636 / 0212-CIP-9	6846

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,649

Applicant(s)

BEELEY ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040105;20040805.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. The Sequence Listing filed September 8, 2004 has been approved.
2. The disclosure is objected to because of the following informalities: The status of the U.S. non-provisional patent applications, e.g., at page 16, line 20, and page 17, line 18, of the specification should be updated. At page 21, line 3, "naphthylalanine" is misspelled.

Appropriate correction is required.

3. Claims 4, 9, 14, 19, 24, 29, 34, 39, 44, 49, 54, 59, 64, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4, 14, 24, 34, 44, 54, and 64 recite that "GLP-1 is selected from the group consisting of GLP-1 (7-36)NH₂, GLP-4(7-37), GLP-1(9-36) and exendin-4." However, "GLP-1" is not a generic group of peptides, but rather is a single peptide having a specific amino acid sequence (see, e.g., page 4, line 30 - page 5, line 1, of Applicants' specification). It may be that in these claims, Applicants intended to recite "said compound" or "the agonists and analogs" (compare, e.g., claim 1, lines 2-3) instead of "GLP-1". Claims 9, 19, 29, 39, 49, 59, and 69 are indefinite because it is not clear if the PPAR inhibitors are to be limited to the specific examples recited in the parenthetical phrases. It is suggested that these parenthetical phrases could be deleted and made the subject matter of further dependent claims. Also with respect to these same claims, the use of the trademarks "Rezulin", "Avandia", and "Actos" is unclear because a trademark denotes a source of goods rather than the goods themselves. To the extent that the trademarks may not be intended as claim limitations, it is not clear why they are used in the claims. See, e.g., MPEP 2173.05(u).

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4. Applicant is advised that should claim 4 be found allowable, claim 34 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 4 and 34 are identical in scope. It is believed that claim 34 should instead depend upon claim 32.

5. Applicants are requested to check the name of the compound "GLP-4(7-37)" in claims 4, 14, 24, 34, 44, 54, and 64. The examiner can find no mention of "GLP-4" or of any GLP-4 analogs in the specification. It may be that this is a misspelling of "GLP-1(7-37)".

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/317,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '126 application anticipate the instant claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-71 are directed to an invention not patentably distinct from claims 1-18 of commonly assigned U.S. patent application 10/317,126. Specifically, see the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. patent application 10/317,126, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

8. Instant claims 1-71 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 10/317,126 because the parent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the administration of exendin or agonists or analogs thereof (note that the disclosure at page 13, line 9 - page 14, line 12, of the parent

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application is limited to three specific extendins, and does not mention agonists or analogs of extendins); does not disclose administering GLP-1(9-36) (note that the disclosure at, e.g., page 9, line 23, requires the analog to be amidated); and does not disclose the genus of compounds excluding the peptide of SEQ ID NO:9, i.e. exendin 4 (NH₂) (the parent application only discloses exendin 4 in unamidated form, and silence in the disclosure does not constitute support for a negative claim limitation - see *Ex parte Grasselli*, 231 USPQ 393, *aff'd on reconsideration* 231 USPQ 395 (Bd. App. 1983)). Accordingly, U.S. Patent Application Publication 2004/0029784, which was published based upon parent application 10/317,126 and has a different inventorship than the instant application, is available as prior art against these claims under 35 U.S.C. 102(e).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

10. Claims 1-71 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2004/0029784. The U.S. Patent Application Publication '784 was published based upon U.S. patent application 10/317,126, which forms the basis of the provisional obviousness-type double patenting rejection set forth above. Claims 1-18 of the U.S. Patent Application Publication '784 clearly anticipate the instant claims.

11. Claims 1-6, 9, 11-16, 19, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Knudsen (U.S. Patent Application Publication 2004/0180824). Knudsen teaches and claims treating polycystic ovarian syndrome by administering a combination of an exendin-4 compound and a thiazolidinedione insulin sensitizer. The exendin-4 compound can be exendin-4. The sensitizer can be troglitazone, rosiglitazone, or pioglitazone. The subject to be treated can be a human. Administration can be subcutaneous or by means of an infusion pump, and can be either sequential or concurrent. See, e.g., paragraph [0041] and [0076], and claims 1, 2, 5, 16, 19, and 29.

Knudsen is available as prior art under 35 U.S.C. 102(e) against the instant claims because the subject matter disclosed in Knudsen and relied upon in the rejection is also disclosed in Knudsen's priority document, provisional application 60/431,999. The subject matter disclosed in Knudsen and relied upon in the rejection is entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/431,999 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the subject matter. See, e.g., page 89, lines 23-34; page 13, lines 23-25; and claims 1, 2, 6, 13, 16, and 24 of the provisional application. This provisional application can be viewed at, and/or a copy ordered from, Public PAIR at <http://portal.uspto.gov/external/portal/pair>.

12. Claims 1-4, 12-14, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Fryburg et al (U.S. Patent No. 6,610,746). Fryburg et al teach treating patients having or at risk of having polycystic ovary syndrome by administering a combination of a sulfonylurea and/or a non-sulfonylurea K^+ ATP channel blocker, a cAMP phosphodiesterase type 3 inhibitor, and another agent. The other agent is preferably GLP-1(7-37) or GLP-1 (7-36)-NH₂. The patients can be human. Administration can be subcutaneous and can be in sustained release form. See column 6, lines 4-7; column 8, lines 22-35; column 14, lines 38-57; and column 15, lines 7-9.

13. Claims 5, 15, and 25 are rejected under 35 U.S.C. 103(a) as being obvious over Fryburg et al (U.S. Patent No. 6,610,746). Application of Fryburg et al is the same as in the above rejection of claims 1-4, 12-14, and 22-24. Fryburg et al do not teach administering their active agents using an infusion pump or by subcutaneously injecting a slow release formulation. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the active agents of Fryburg et al using an infusion pump or by

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subcutaneously injecting a slow release formulation because Fryburg et al is not limited to any particular means of administration, because these are known means of administration, and because these means of administration have the benefit of permitting sustained treatment without the patient having to remember and maintain a sustained dosage schedule.

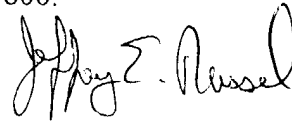
14. Odaka et al (U.S. Patent No. 6,329,403) is cited as art of interest, but is not deemed to teach or suggest the instant claimed invention. While Odaka et al teach the possible use of GLP-1 or its analogs or agonists (see column 11, lines 29-36), in combination with an insulin sensitizer and an anorectic, in preventing or treating diabetes, and teach the possibility of preventing or treating PCOS (see column 12, lines 48-52) using the disclosed compositions, there is not deemed to be sufficient motivation to use GLP-1 or its analogs or agonists specifically to treat PCOS specifically.

Mogensen et al (U.S. Patent No. 6,569,901, see especially column 24, lines 52-55, and column 30, lines 28-32) is cited as art of interest, being essentially duplicative of the references applied and/or discussed above.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Russel" clearly distinguishable.

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

November 4, 2004